

**PUBLIC VERSION – REDACTED**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NOVOZYMES A/S,

Plaintiff,

v.

C.A. No. 05-160-KAJ

GENENCOR INTERNATIONAL, INC. and  
ENZYME DEVELOPMENT CORPORATION,

Defendants.

**DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION FOR LEAVE TO MODIFY THE  
SCHEDULING ORDER FOR THE PURPOSE OF AMENDING ITS COMPLAINT**

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### I. INTRODUCTION

Novozymes A/S (“NZDK”)<sup>1</sup> rushed to file this case the very day its U.S. Patent No. 6,867,031 (“’031 Patent”) issued. The day it filed, NZDK was aware of every single fact and agreement upon which it now bases its request to add another company, its indirect subsidiary Novozymes North America, Inc. (“NZNA”), as a “co-plaintiff” in this case. Yet, NZDK concealed those facts and agreements for well more than a year, even in the face of Defendants’ explicit discovery requests, and the relevance of this information to issues such as standing, NZDK’s request for preliminary injunctive relief, issues at the liability trial, and dispositive motions on damages. Only when NZDK realized that its voluntary, otherwise beneficial, corporate structuring and licensing arrangements might limit or preclude its damages claim (and perhaps its entitlement to injunctive relief), did it suddenly raise the issue of joining NZNA as a co-plaintiff and (after repeated requests) produce the agreements on which it bases its motion. NZDK’s late production of documents came after the deadline to file dispositive motions on damages, to the great prejudice of Defendants as such documents provide a basis for a summary judgment motion to preclude NZDK from seeking the lost profits of NZNA.<sup>2</sup>

Too little, even if not too late – those agreements and NZDK’s admission that NZNA is a non-exclusive licensee to the ’031 Patent unequivocally demonstrate that NZNA does not have standing to assert the ’031 Patent (whether alone or with NZDK). Further, NZDK’s reliance on NZNA’s sales of products that compete with Defendants’ Spezyme® ETHYL, alleged economic injury, and a purported “close nexus” between NZDK and NZNA as bases for standing is misplaced.

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<sup>1</sup> Defendants adopt the “NZDK” label for convenience in responding to this motion. Notably, Novozymes A/S did not use this label until it untimely revealed the documents at issue and requested that “NA” be joined as a co-plaintiff.

<sup>2</sup> Defendants request that the Court give them leave to file a Motion for Summary Judgment on this issue.

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- None of the products NZNA manufactures and sells (nor any products for that matter) practice the '031 Patent, thus such manufacturing and sales could never confer proprietary rights in the '031 Patent.
- NZNA has not suffered a legal injury which could give rise to a patent infringement suit; economic injury alone simply does not suffice.
- Reliance on an alleged “close nexus” would effectively do away with the corporate structure that NZDK itself created for its own admitted benefit. NZDK should not be allowed to take advantage of its corporate structure for tax purposes while at the same time concealing its disadvantages in litigation.

In short, NZNA has no interest in the '031 Patent sufficient to confer standing, and cannot be a “co-plaintiff” in this action, as a matter of law. For this and many other reasons, NZDK’s motion lacks good cause and is untimely, prejudicial, and utterly futile. It should be denied.

### II. BACKGROUND

#### A. Procedural History

This case began nearly a year and a half ago on March 15, 2005, when NZDK filed its complaint against Defendants Genencor International, Inc. and Enzyme Development Corporation (collectively “Genencor”), the day the '031 Patent issued. *See* Complaint, Docket Item (“DI”) 1. NZDK has been the owner of the '031 Patent throughout this litigation. *See* Complaint, DI 1 and Proposed Pretrial Order, DI 101. NZDK filed a preliminary injunction motion on June 22, 2005. *See* Plaintiff’s Preliminary Injunction Motion, DI 16. On July 5, 2005, the Court issued a Scheduling Order, which set August 31, 2005 as the deadline for all motions to join other parties and amend or supplement the pleadings. *See* Scheduling Order, DI 32 at 2.

The parties formally began the discovery process and conducted discovery throughout the Summer and Fall of 2005. *See* Notice of Service, DI 30 (Defendants’ 07/01/05 First Sets of Interrogatories and Document Requests) and Notice of Service, DI 31 (Novozymes A/S 07/05/05 First

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Sets of Interrogatories and Document Requests). While the parties' primary focus during this time period was on gathering information and documents relating to the preliminary injunction motion, the Court's July 5, 2005 Scheduling Order clearly set forth a discovery cut-off date (February 3, 2006) as well as a trial date (six day bench trial commencing on October 10, 2006). *See* Scheduling Order, DI 32 at 3 and 8. The parties were aware that discovery pertained to the entire litigation, including information and documents concerning damages issues. For example, on July 5, 2005, NZDK served at least twelve document requests and three interrogatories, which its counsel later described as "relevant to the damages issues in this case." *See* Declaration of Jane L. Froyd ("Froyd Decl."), Ex. A, 05/23/06 email from George Hykal to Greg Lanier and Jane Froyd (requesting updated responses to previously served discovery requests "relevant to damages" and listing these requests therein); Ex. B, Novozymes A/S First Set of Interrogatories; Ex. C, Novozymes A/S First Set of Requests for the Production of Documents and Things. NZDK's requests sought documents relating to sales and pricing of the Spezyme® ETHYL product, costs incurred, financial statements, customer information, product comparisons, market information, etc. *See* Froyd Decl., Exs. B and C. Genencor's first discovery requests also sought damages-related documents, including "[a]ll documents relating to any license or offer to license of the patent-in-suit related to the alleged invention of the '031 patent," and "[a]ll documents relating to any offer by you to assign or sell any interest in the patent-in-suit." *See* Froyd Decl., Ex. D, 06/07/06 email from Jane Froyd to Robert Sullivan and George Hykal (requesting updated responses to previously served document requests and listing these requests therein); Ex. E, Defendants' First Request for the Production of Documents and Things.

On October 24, 2005, the Court denied NZDK's preliminary injunction motion. *See* Memorandum Order, DI 68. Four days later, the Court issued the First Amended Scheduling Order which, among other things, bifurcated this case. *See* October 28, 2005 First Amended Scheduling Order, DI 70. The Court expedited the liability trial and scheduled it for a three day bench trial commencing on

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March 6, 2006, while the damages trial was scheduled for a three day bench trial commencing on October 10, 2006.

After the case was bifurcated in October 2005, the parties primarily focused on the liability trial, which took place on March 6-9, 2006. Discovery on damages issues resumed in May 2006. *See* Notice of Service, DI 128 (Novozymes A/S 05/26/06 Second Set of Requests for the Production of Documents and Things) and Notice of Service, DI 129 (Defendants' 06/07/06 Second Request for the Production of Documents and Things). Notably, Defendants continued to request relevant licensing documents, including “[a]ll documents and things that refer or relate to any and all licenses entered into or proposed regarding any Novozymes' industrial enzyme, during the period of January 1, 2000 to the present, including without limitation license agreements and documents concerning the negotiations for these license agreements.” *See* Froyd Decl., Ex. F, Defendants' 06/07/06 Second Request for the Production of Documents and Things, Request No. 29. The July 3, 2006 deadline to file dispositive motions on damage passed without either party filing a motion.

It was not until July 18, 2006 that NZDK's counsel first raised the issue of joining NZNA as a co-plaintiff in this lawsuit, first informally in a telephone conversation, which was memorialized in an email later that day. *See* Froyd Decl., Ex. G, 07/18/06 email from George Hykal to Jane Froyd and Greg Lanier seeking Defendants' consent to amend the complaint to join NZNA as a co-plaintiff. In this email

NZDK's counsel stated that it believed [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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NZDK then produced to Genencor, for the first time, these three agreements. *See id.*

## B. Relationship Between NZDK and NZNA

In its moving papers, and in the Olofson Declaration thereto, NZDK states that NZNA is an indirect (through a U.S. holding company), wholly owned subsidiary of NZDK. *See Novozymes A/S Brief in Support of its Motion for Leave to Modify the Scheduling Order for the Purpose of Amending its Complaint (“NZDK Brief”), DI 145 at 2, 4; Declaration of Richard Olofson (“Olofson Decl.”) at ¶¶ 4-6.*

A series of eleven horizontal black bars of varying lengths, decreasing from left to right. The bars are evenly spaced and extend across most of the width of the frame.

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**C. Certain Agreements Between NZDK and NZNA**

(1) 01/01/96 Technology License Agreement

(2) 01/01/01 Framework Agreement for Services

<sup>3</sup> NZDK also belatedly produced additional agreements between it and NZNA, about which Mr. Olofson testified. *See* Froyd Decl., Ex. K, Olofson Dep. at 177:18-186:13. These agreements provide further proof that NZDK and NZNA treat each other as separate corporate entities, requiring formal contractual agreements to exchange rights and services. Genencor does not specifically address these agreements herein as they are not relied upon by NZDK in support of its standing argument.

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(3) 01/01/05 Marketing Agreement

The image consists of a vertical column of ten horizontal black bars. Each bar has a slightly irregular, wavy texture. The bars decrease in length from top to bottom, starting with a long bar at the top and ending with a very short bar at the bottom.

### **III. ARGUMENT**

## A. Summary of Argument

NZNA may not now join, nor could it ever have been a party to, this lawsuit because it lacks standing to sue. At most, NZNA has a bare, non-exclusive license to the '031 Patent; such a license can never confer standing on a licensee as it does not grant any proprietary rights in a patent. Further, NZDK's Motion for Leave to Modify the Scheduling Order for the Purpose of Amending its Complaint should be denied under Rule 16(b) of the Federal Rules of Civil Procedure as NZDK has not established

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good cause for its failure to timely make this motion. Finally, NZDK's Motion should also be denied under Rule 15(a) of the Federal Rules of Civil Procedure based on NZDK's undue delay in filing the motion, the prejudice it causes Defendants, and the futility of the motion.

**B. NZNA Does Not Have Standing**

(1) Standing to Sue for Patent Infringement

Standing to sue is a threshold requirement in every federal action. *See Sicom Sys. Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 975 (Fed. Cir. 2005); *Pfizer, Inc. v. Elan Pharm. Research Corp.*, 812 F. Supp. 1352, 1356 (D. Del. 1993). Standing must be present at the time the suit is brought. *See Sicom Sys.*, 427 F.3d at 975-76; *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 917 F. Supp. 305, 309-10 (D. Del. 1995). The party bringing the action bears the burden of establishing that it has standing. *See Sicom Sys.*, 427 F.3d at 976; *Pfizer*, 812 F. Supp. at 1356.

In addition to constitutional standing,<sup>4</sup> standing to sue for patent infringement is specifically controlled by the Patent Act, which provides that a “patentee shall have remedy by civil action for infringement of his patent.” 35 U.S.C. § 281. Generally, only a patentee or assignee has standing to bring a patent infringement suit. *See id.; Abbott Labs v. Diamedix Corp.*, 47 F.3d 1128, 1130 (Fed. Cir. 1995). Title 35 defines “patentee” as the party to whom the patent was issued or any successors in title to the patent. *See 35 U.S.C. § 100(d)*. A licensee is not entitled to bring suit in its own name as a patentee, unless it is an exclusive licensee holding “all substantial rights,” in the patent (*i.e.*, the rights to exclude others from making, using or selling the invention). *See Sicom Sys.*, 427 F.3d 971, 976; *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001); *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998); *Intuitive Surgical, Inc. v. Computer Motion, Inc.*, 214

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<sup>4</sup> The requirement of standing is both a constitutional limitation on federal court jurisdiction and a prudential limitation on its exercise. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). The constitutional requirements for standing emanate from Article III of the United States Constitution, which states that federal courts may only adjudicate cases or controversies. *See Allen v. Wright*, 468 U.S. 737, 750-51 (1984). Constitutional standing requires only that the plaintiff have suffered an injury in fact, that there be a causal connection between the injury and the defendant’s conduct, and that the injury be redressable by a favorable court decision. *See Lujan*, 504 U.S. at 560.

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F. Supp. 2d 433, 439 (D. Del. 2002); *Monsanto Co. v Aventis Cropscience SA*, 226 F. Supp. 2d 531, 538 (D. Del. 2002). Such a licensee is in effect an “assignee” and therefore a patentee. *See Textile Prods.*, 134 F.3d at 1484. Where the exclusive licensee has some, but not all of the substantial rights in the patent, it has standing to sue third parties only as a co-plaintiff with the patentee. *See id.*; *Sicom Sys.*, 427 F.3d at 976; *Intellectual Prop. Dev.*, 248 F.3d at 1345; *Intuitive Surgical*, 214 F. Supp. 2d at 439; *Monsanto*, 226 F. Supp. 2d at 538.

Conversely, a non-exclusive, or “bare,” licensee, *i.e.*, one that simply has “a covenant by the patent owner not to sue the licensee for making, using, or selling the patented invention and under which the patent owner reserves the right to grant similar licenses to other entities,” has no constitutional standing under the Patent Act to bring suit or even to join a suit with the patentee. *Intuitive Surgical*, 214 F. Supp. 2d at 439 quoting *Intellectual Prop. Dev.*, 248 F.3d at 1345 (citations omitted). *See also General Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, 181 (1938) (stating that a non-exclusive license is nothing more than “a mere waiver of the right to sue”); *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891); *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 956 (Fed. Cir. 2006); *Sicom Sys.*, 427 F.3d at 976; *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1552 (Fed. Cir. 1995); *Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1030 (Fed. Cir. 1995); *Affinion Loyalty Group, Inc. v. Maritz, Inc.*, No. Civ. A. 04-360-JJF, 2006 WL 1431065, at \*2 (D. Del. May 22, 2006). This is because the non-exclusive licensee lacks the requisite “legal ownership” of the patent; it does not hold any of “the proprietary sticks from the bundle of patent rights.” *Ortho Pharm.* 52 F.3d at 1031. In other words, a non-exclusive licensee of a patent has only a personal interest in the patent, not a legal interest, and therefore suffers no legal injury from infringement. *See Sicom Sys.*, 427 F.3d at 976; *Rite-Hite Corp.*, 56 F.3d at 1552; *Ortho Pharm.*, 52 F.3d at 1031 (stating that a non-exclusive licensee “suffers no legal injury from infringement and, thus, has no standing to bring suit or even join in a suit with the patentee.... [E]conomic injury alone does not provide standing to sue under the patent statute.”). As the Second Circuit explained long ago in an oft-cited case:

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In its simplest form, a license means only leave to do a thing which the licensor would otherwise have a right to prevent. Such a license grants to the licensee merely a privilege that protects him from a claim of infringement by the owner of the patent monopoly.... He has no property interest in monopoly of the patent, nor any contract with the patent owner that others shall not practice the invention. Hence the patent owner may freely license others, or may tolerate infringers, and in either case no right of the patent licensee is violated. Practice of the invention by others may indeed cause him pecuniary loss, but it does him no legal injury.... Infringement of the patent can no more be a legal injury to a bare licensee than a trespass upon Blackacre could be an injury to one having a nonexclusive right of way across Blackacre.

*Western Elec. Co. v. Pacent Reproducer Corp.*, 42 F.2d 116, 117 (2d Cir. 1930) (citations omitted). See also *Textile Prods.*, 134 F.3d at 1484; *Ortho Pharm.*, 52 F.3d at 1031; *Innis Speiden & Co. v. Food Mach. Corp.*, 2 F.R.D. 261, 264-65 (D. Del. 1942).

Whether a licensee is an exclusive licensee or a non-exclusive licensee is determined by the intent of the parties to the license, as manifested by the terms of their agreement and by examining the substance of the grant. See *Textile Prods.*, 134 F.3d at 1484; *Ortho Pharm.*, 52 F.3d at 1033-34; *Intuitive Surgical*, 214 F. Supp. 2d at 439. Standing cannot be “inferred argumentatively from averments in the pleadings,” but rather ‘must affirmatively appear in the record.’” *Intuitive Surgical*, 214 F. Supp. 2d at 439-40 quoting *Grace v. American Cent. Ins. Co.*, 109 U.S. 278, 284 (1883) and *Mansfield, C. & L.M.R. Co. v. Swan*, 111 U.S. 379, 382 (1884).

(2) NZNA is a “Non-Exclusive Licensee” and Therefore Does Not Have Standing

In this case, NZDK affirmatively admits that NZNA is a non-exclusive licensee. Twice in its brief, NZDK explicitly states that NZNA “is a non-exclusive licensee of the ’031 Patent.”<sup>5</sup> See NZDK Brief, DI 145 at 3. Such an admission on the part of NZDK makes this Court’s ruling quite easy; the law is well established that non-exclusive licensees never have standing to sue for patent infringement. See *Sicom Sys.*, 427 F.3d at 976; *Rite-Hite Corp.*, 56 F.3d at 1552; *Ortho Pharm.*, 52 F.3d at 1030; *Schreiber*

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<sup>5</sup> Technically, NZDK says this only once as the second time it states that “NZDK” is the non-exclusive licensee; however, Defendants believe that this is simply a typographical error and that NZDK intended to restate its assertion that NZNA is a non-exclusive licensee. If NZDK is a licensee and not the owner of the ’031 Patent, many other issues arise.

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*Foods, Inc. v. Beatrice Cheese, Inc.*, 305 F. Supp. 2d 939, 950 (E.D. Wis. 2004), *rev'd on other grounds*, 402 F.3d 1198 (Fed. Cir. 2005).

NZDK's admission is consistent with the terms of the only agreement in the record that arguably gives NZNA a bare license. [REDACTED]

In its brief, NZDK also relies on the January 1, 2001 Framework Agreement for Services (“Service Agreement”), [REDACTED]

<sup>6</sup> In its brief, NZDK also references a “Marketing Agreement.” NZDK does not rely on the Marketing Agreement as proof of NZNA’s non-exclusive license, rather it references this agreement in connection with its “sole licensee” theory of standing. Accordingly, Defendants address the Marketing Agreement in response to this theory. *See infra* at 16.

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The image consists of a grid of horizontal black bars. There are approximately 20 rows of bars. Each row contains between 1 and 5 bars. The bars are solid black and have thin white borders. They are arranged in a staggered pattern where each row is offset from the one above it. The lengths of the bars vary significantly, with some being very short and others extending almost to the edge of the frame.

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[REDACTED]

Based on NZDK's admissions, even reading the Technology License in a light most favorable to NZDK, NZNA is simply a non-exclusive licensee without standing, and therefore may not be joined to this case.

(3) NZDK's Reliance on *Kalman* Is Misplaced

NZDK bases its entire argument regarding NZNA's purported standing to sue on one Federal Circuit court decision, *Kalman v. Berlyn Corp.*, 914 F.2d 1473, 1479-82 (Fed. Cir. 1990). *Kalman* actually supports Defendants' argument that NZNA does not have standing, as it reaffirms the "well settled [principle] that a non-exclusive licensee of a patent has no standing to sue for infringement." *Kalman*, 941 F.2d at 1481. See also *Abbott Labs.*, 47 F.3d at 1131 (citing *Kalman* for principle that non-exclusive licensee has no standing); *Wang Labs., Inc. v. Oki Elec.*, 15 F. Supp. 2d 166, 171-72 (D. Mass. 1998) (citing *Kalman* for principle that non-exclusive licensee has no standing).

NZDK would have this Court believe that *Kalman* sets forth an exception to the general rule that non-exclusive licensees do not have standing. The license at issue in *Kalman*, however, was an implied exclusive license,<sup>7</sup> not a non-exclusive license (such as NZNA's license), and thus it is not analogous to the license at issue in this case.

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<sup>7</sup> To be fair, the *Kalman* court does not specifically call PDL an "implied exclusive licensee," but this is the logical reading of the case as evidenced by: a) subsequent courts' interpretations of *Kalman* as finding an implied exclusive license, see *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 361 F. Supp. 2d 210, 215-16 (S.D.N.Y. 2005); *Schreiber*, 305 F. Supp. 2d at 953 (distinguishing *Kalman* because it "did not involve non-exclusive licensees"); *Carver v. Velodyne Acoustics, Inc.*, 202 F. Supp. 2d 1147, 1149 (W.D. Wash. 2002) (stating that "[a]t most, *Kalman* stands for the proposition that a patentee can recover profits of a separate corporation that is an exclusive licensee"); *Ricoh Co. Ltd. v. Nashua Corp.*, 947 F. Supp. 21, 24 (D.N.H. 1996); *Ropak Corp. v. Plastican, Inc.*, No. 04-C-5422, 2005 WL 2420384, at \*1 (N.D. Ill. Sept. 30, 2005); *Polyclad Laminates, Inc. v. MacDermid, Inc.*, Civ. No. 99-162-M, 2001 WL 274722, at \*3 (D.N.H. Feb. 13, 2001); *Blumenthal v. Barber-Colman Holding Corp.*, No. 90 C 20365, 1991 WL 352525, at \*2 (N.D. Ill. Nov. 26, 1991); b) the fact that other Federal Circuit decisions have also found that exclusive licenses may be implied in particular factual circumstances, see *Rite-Hite*, 56 F.3d at 1552-53; *Weiner v. Rollform*, 744 F.2d 797, 806-07 (Fed. Cir. 1984), cert. denied, 470 U.S. 1084 (1985); and c) the clear law of the Federal Circuit, as specifically articulated in *Kalman* itself, that non-exclusive licensees have no standing to sue for patent infringement. See *Kalman*, 941 F.2d at 1481.

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*Kalman* addressed a suit brought by an inventor/patentee, Dr. Kalman. Dr. Kalman, together with his brother, formed an entity, “PDL,” to specifically manufacture and market a device that practices the patent at issue in the case. *See* 914 F.2d at 1475. While there was no formal, explicit license agreement transferring the rights to exclude others from making, using, and/or selling the patented invention, the court found there to be an implied exclusive license between Dr. Kalman and PDL based on the particular facts of the case, namely that PDL was the only entity that marketed and sold the patented invention (and actually did so), that PDL was “directly damaged” by an infringer in a two supplier market, and a particularly close nexus between PDL and Dr. Kalman. *See id.* Thus, based on this implied exclusive license, the court allowed Dr. Kalman to amend the complaint to add PDL as a co-plaintiff. *See id.*

There is an important and dispositive distinction between *Kalman* and this case – the licensee in *Kalman* manufactured and sold products that practiced the patent. *See Kalman*, 914 F.3d at 1482 (stating that it is “clear to all parties that the Autoscreen device, manufactured and marketed solely by PDL, is an embodiment of the device claimed in the ‘017 patent”). Together with the facts that PDL was the only entity manufacturing and selling the patented device and that PDL was the company that the patentee and his brother created for this very purpose, the *Kalman* court found that PDL exclusively held some proprietary rights of the patent-in-suit such that it had standing to join as a co-plaintiff. Subsequent cases that rely on *Kalman* and find that a licensee has standing to sue consistently involve third-parties that manufacture, sell, and/or use products that practice the patent; they do not involve third-parties who have licenses solely based on a covenant not to sue or who manufacture and sell products that do not practice the patent. *See e.g., McNeilab, Inc. v. Scandipharm, Inc.*, No. 94-1508, 1996 WL 431352, at \*1-2 (Fed. Cir. July 31, 1996); *Schneider AG v. SciMed Life Sys., Inc.*, No. 94-1317, 1995 WL 375949, at \*2 (Fed. Cir. 1995); *Site Microsurgical Sys., Inc. v. Cooper Cos., Inc.*, 797 F. Supp. 333, 338 (D. Del. 1992) (holding that parent company with “no license of any kind and [that] is not marketing the patented technology on behalf of the patentee” has no standing to sue); *Loegering Mfg., Inc. v. Grouser Prods., Inc.*, 330 F. Supp. 2d 1057, 1073-74 (D.N.D. 2004); *Ricoh Co.*, 947 F. Supp. at 24.

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Without this essential fact, the *Kalman* court would not have even considered the other facts that it weighed in connection with its standing determination. Specifically, the court noted that PDL was “directly damaged” by the infringer in a two player market (*i.e.* lost profits could directly be attributed to the infringing sales), however if PDL did not have a proprietary interest in the patent (its exclusive right to manufacture and sell the patented product), such that it suffered a legal injury because of the infringement, then “direct damages” would be irrelevant because economic injury alone cannot confer standing. *See Ortho Pharm.*, 52 F.3d at 1030. Further, the “close nexus” between Dr. Kalman and PDL considered by the court (*i.e.*, an inventor and the company he created for the purpose of manufacturing and selling his patented product), would be of no import if PDL did not have a proprietary interest in the patent; courts have repeatedly rejected efforts to blur the lines between legal entities for standing purposes, regardless of the their affiliation. *See Merial Ltd v. Intervet, Inc.*, 430 F. Supp. 2d 1357, 1362 (N.D. Ga. 2006) (holding that parent company with non-exclusive license has no standing); *DePuy, Inc. v. Zimmer Holdings, Inc.*, 384 F. Supp. 2d 1237, 1239 (N.D. Ill. 2005) (Posner, J. sitting by designation) (dismissing case because the corporate parent of a patent owner lacked standing to sue for infringement); *Schreiber Foods*, 305 F. Supp. 2d at 953-54 (holding that parent company with non-exclusive license has no standing; “corporate plaintiff in a patent infringement case cannot have it both ways” by taking advantage of corporate form while at the same time denying its disadvantages); *Carver*, 202 F. Supp. 2d at 1149 (holding that manufacturing entity has no standing; a party “may not … take advantage of the corporate form and simultaneously shun its disadvantages”); *Lans v. Digital Equip. Corp.*, 84 F. Supp. 2d 112, 123 (D.D.C. 1999), *aff'd*, 252 F.3d 1320 (Fed. Cir. 2001) (holding that sole shareholder of patent holding company, which is also managing director of company, does not have standing to sue for infringement; “the law generally does not allow the option of ‘reverse piercing’ the corporate veil when it suits the corporation’s owner”); *Blumentahl*, 1991 WL 352525, at \*2-3 (holding that sole manufacturing licensee which is wholly owned by the patent owner has no standing).

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In this case, NZNA does not market and sell any products that practice the '031 Patent, because no such products exist. *See* Davis Report at A-89; Froyd Decl., Ex. K, Olofson Dep. at 190:11-25. Thus, the crucial and necessary factor upon which *Kalman* bases standing is absent here. NZDK attempts to gloss over this issue in its brief by relying on the Marketing Agreement and NZNA sales of the Liquozyme product (which does not practice the alleged invention of the '031 Patent). Citing to the Marketing Agreement, NZDK claims that it has the "exclusive right to manufacture, sell, and distribute in the United States any products embodying any NZDK patented invention, including any embodiments of the invention claimed in the '031 Patent. ... Accordingly, NZNA is the sole manufacturer, marketer, and distributor of Liquozyme in the United States." *See* NZDK Brief, DI 145 at 3 and 10. This is a flagrant misreading of the Marketing Agreement.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] To cite to this Agreement followed by a reference to a product that does not practice the patent is not only misleading, it is downright deceptive.

Further, even if the "close nexus" consideration discussed in *Kalman* had any relevance to the determination of whether NZNA has standing in this case, the relationship between NZDK and NZNA is easily distinguishable from that of Dr. Kalman and PDL. In *Kalman*, the parties were the inventor/patentee and the company he created to manufacture and sell his patented product. Here, we have two sophisticated and distinct corporate entities, which maintain their separate corporate status for

[REDACTED] Courts "view skeptically" requests to ignore the corporate form when such requests come from the party responsible for establishing

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the corporation.” *Schreiber*, 305 F. Supp. 2d at 953 (holding that patentee’s parent company who had a non-exclusive license did not have standing), citing *McCarthy v. Azure*, 22 F.3d 351, 362-63 (1st Cir. 1994), 1 William Meade Fletcher, *Fletcher Encyclopedia of the Law of Private Corporations* § 43 (rev. ed. 1999) (stating that “[t]here is a presumption of separateness” and that “even when the parent exercises domination and control over the subsidiary, corporate separateness will be recognized”). In fact, the Federal Circuit specifically refused to dispense with corporate structure in a case where a patentee did not practice the patent and the sales of products that competed with the infringing product were made not by the patentee, but by one of its corporate affiliates. *See Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004) (holding that a patentee could not recover lost profits on sales by its sister corporation). The *Poly-America* court stated that a patentee “may not enjoy the advantages of ... separate corporate structure[s] and, at the same time, avoid the consequential limitations of that structure – in this case, the inability of the patent holder to claim the lost profits of its non-exclusive licensee.” *Id.* *See also Carver*, 202 F. Supp. 2d at 1149; *Lans*, 84 F. Supp. 2d at 123. Rather, the “better rule would seem to be that a person who has voluntarily adopted the corporate form to engage in business is precluded from asking courts to disregard that form merely because the person is disadvantaged by its use.” 1 W. Fletcher § 41.70.

In sum, *Kalman* simply does not carve out an exception to the rule that non-exclusive licensees such as NZNA could have standing to sue for patent infringement. Tellingly, NZDK offers no other legal precedent to support this contention. NZDK should not be allowed to join NZNA as a party to this lawsuit because NZNA does not have standing.

**C. There is No Good Cause to Amend the Scheduling Order Under FRCP 16(b)**

This Court should also deny NZDK’s motion to modify the Scheduling Order pursuant to Rule 16(b) of the Federal Rules of Civil Procedure as NZDK has not established good cause to do so at this late date.

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When a party moves to modify a deadline established in the pretrial Scheduling Order, the party must first satisfy Rule 16(b) of the Federal Rules of Civil Procedure, and demonstrate good cause. See *Eastern Minerals & Chems. Co. v Mahan*, 225 F.3d 330, 340 (3d Cir. 2000); *Dimensional Communications, Inc. v. Oz Optics, Ltd.*, 148 F. Appx. 82, 85 (3d Cir. Aug. 12, 2005); *Parker v. Columbia Pictures Indus.*, 204 F.3d 326, 339-40 (2d Cir. 2000); *Gonzalez v. Comcast Corp.*, No. Civ. A. 03-445-KAJ, 2004 WL 2009366, at \*1 (D. Del. Aug. 25, 2004); *GlobespanVirata, Inc. v. Texas Instruments Inc.*, No. Civ. A. 03-2854 (GEB), 2005 WL 1638136, at \*3-4 (D.N.J. July 12, 2005).

NZDK would have the Court conflate the standard under Rule 16(b) with the more lenient standard of Rule 15(a), which governs motions to amend pleadings. However, the Third Circuit and numerous other appellate courts have specifically ruled that Rule 16(b)'s "good cause" standard, and not Rule 15(a)'s more liberal standard, governs a motion to amend filed after the deadline a district court has set for amending a pleading. See *Eastern Minerals*, 225 F.3d at 339-40; *Dimensional Communications*, 148 Fed. Appx. at 85; *S & W Enters., L.L.C. v. SouthTrust Bank of Alabama*, 315 F.3d 533, 536 (5th Cir. 2003) (ruling that "Rule 16(b) governs amendment of pleadings after a scheduling order deadline has expired"); *Leary v. Daeschner*, 349 F.3d 888, 909 (6th Cir. 2003) (stating that "[o]nce the scheduling order's deadline passes, a plaintiff first must show good cause under Rule 16(b) for failure earlier to seek leave to amend before a court will consider whether amendment is proper under Rule 15(a)"); *Parker*, 204 F.3d at 340 (holding that "despite the lenient standard of Rule 15(a), a district court does not abuse its discretion in denying leave to amend the pleadings after the deadline set in the scheduling order where the moving party has failed to establish good cause"); *In re Milk Prods. Antitrust Litig.*, 195 F.3d 430, 437-38 (8th Cir. 1999); *Sosa v. Airprint Sys., Inc.*, 133 F.3d 1417, 1419 (11th Cir. 1998) (noting that "if we considered only Rule 15(a) without regard to Rule 16(b), we would render scheduling orders meaningless and effectively would read Rule 16(b) and its good cause requirement out of the Federal Rules of Civil Procedure"); *Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 610 (9th Cir. 1992) (noting that Rule 16's standards may not be "short-circuited" by those of Rule 15 because "[d]isregard of the [scheduling]

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order would undermine the court’s ability to control its docket, disrupt the agreed-upon course of the litigation, and reward the indolent and the cavalier”); *Riofrio Anda v. Ralston Purina Co.*, 959 F.2d 1149, 1154-55 (1st Cir. 1992).

Rule 16(b) provides that a pretrial Scheduling Order “shall not be modified except upon a showing of good cause and by leave of the District Judge.” Fed. R. Civ. P. 16(b). Good cause depends on the diligence of the moving party. *See GlobespanVirata*, 2005 WL 1638136, at \*3, citing *Rent-A-Center v. Mamaroneck Ave. Corp.*, 215 F.R.D. 100, 104 (S.D.N.Y. 2003) (citations omitted). The moving party must show that despite its diligence, it could not reasonably have met the scheduling order deadline. *See id.*; *S & W Enters.*, 315 F.3d at 535. Moreover, “the lack of prejudice to the nonmovant does not show ‘good cause.’” *See id.*, citing *Deghand v. Wal-mart Stores, Inc.*, 904 F. Supp. 1218, 1221 (D. Kan. 1995) (citations omitted).

In this case, the only justification that NZDK posits for not timely moving to amend the complaint is that the addition of NZNA is only relevant for damages purposes and that because this case was bifurcated into liability and damages phases, the parties only recently began focusing on the issue of damages at which time “the addition of NZNA as a co-plaintiff became of moment to NZDK.” *See* NZDK Brief, DI 145 at 1 and 9. This is simply not true.

First, this case was not bifurcated until October 28, 2005, over four months after NZDK filed its preliminary injunction motion and two months after the deadline for amending the complaint passed. *See* First Amended Scheduling Order, DI 70. The parties did not primarily focus on liability issues until after that date. Prior thereto, the parties believed that discovery for the entire litigation would conclude in February 2006, and had certainly contemplated damages discovery, as evidenced by the fact that each party served discovery requests as early as July 2005 relating to the issues of damages. *See* Notice of Service, DI 30 (Defendants’ 07/01/05 First Sets of Interrogatories and Document Requests) and Notice of Service, DI 31 (Novozymes A/S 07/05/05 First Sets of Interrogatories and Document Requests).

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Second, all of the information and documents upon which NZDK relies to argue that NZNA has standing to join as a co-plaintiff has been within NZDK's control since well before it even filed its complaint against Genencor. Further, documents such as the recently produced Technology License, Services Agreement, and Marketing Agreement are responsive to document requests Genencor served on July 1, 2005 as well as document requests served on June 7, 2006. Novozymes failed to produce these documents until July 19, 2006, and only after it raised the issue of joining NZNA.

NZDK's delay in filing its motion to amend is most certainly due to a lack of diligence on the part of NZDK. While the issue of adding NZNA may not have occurred to NZDK until after the liability trial, it is the plaintiff in this matter, and it clearly was aware that it intended to seek damages from Genencor. All information and documents upon which NZDR relies to justify its amendment have been in its possession since the beginning of the case, well prior to the Court's deadline to amend pleadings.<sup>8</sup> Good cause to justify this late amendment is entirely absent. Accordingly, this Court should deny NZDK's motion to modify the scheduling order.

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<sup>8</sup> NZDK cites Defendants' amendment of their Answer after the August 31, 2005 scheduling order deadline as evidence that NZDK has good cause for making its own amendment. However, NZDK conveniently ignores that Defendants' amendment was based on information learned during the discovery process and not available to Defendants prior to the deadline to amend. Specifically, the Court allowed Defendants to amend their answer to expand on their inequitable conduct defense with information *learned from NZDK during discovery*. Such amendments are not only routinely granted, but are even encouraged. See e.g., *Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484 (D. Del. 2003) (stating that "since the Rule 9(b) 'pleading with particularity' requirement is implicated with regard to an inequitable conduct claim, [defendant] was prudent and possibly required to confirm the factual allegations through discovery"); *Wyeth v. Teva Pharmas. United States, Inc.*, No. 2:03-cv-01293-WJM-RJH, 2005 U.S. Dist. LEXIS 40055, at \*16 (D.N.J. Aug. 3, 2005) (refusing a motion to amend under Rule 16 because "although *Enzo Life Sciences* was decided in part under Rule 16, the Court expressly found that the inequitable conduct theory was based on a new set of facts discovered after the amendment cutoff date") (citing *Enzo Life Sciences*, 270 F. Supp. at 489) (emphasis added); *ResQNET.com, Inc. v. Lansa, Inc.*, 382 F. Supp. 2d 424, 450 (S.D.N.Y. 2005) (allowing accused infringer to amend its answer to include an inequitable conduct defense based on information acquired through discovery in order to satisfy the heightened pleading requirements of Rule 9(b)). Conversely, NZDK's desired amendment is based on information that it has had in its possession since the inception of the case.

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**D. NZDK May Not Amend Its Complaint Under FRCP 15(a) Due to its Undue Delay in Bringing the Motion, Prejudice to Defendants, and the Futility of the Motion**

Although leave to amend pleadings under Rule 15(a) of the Federal Rules of Civil Procedure is generally freely given, “a court should deny leave to amend if the moving party is guilty of undue delay, bad faith, dilatory motive, prejudice, or his or her amended claims are futile.” *Monahan v. City of Wilmington*, No. Civ. A. 00-505 JJF, 2004 WL 758342, at \*1 (D. Del. Jan. 30, 2004). Courts have denied Rule 15(a) motions based on undue delay alone, as well as based on undue delay in combination as one of only two factors. *See USX Corp. v. Barnhart*, 395 F.3d 161, 166-67 (3d Cir. 2004) (affirming Rule 15(a) denial based solely on undue delay); *Lindquist v. Buckingham Twp.*, 106 Fed. Appx. 768, 775-76 (3d Cir. 2004) (affirming Rule 15(a) denial based solely on undue delay); *Oran v. Stafford*, 226 F.3d 275, 291 (3d Cir. 2000) (affirming Rule 15(a) denial because of undue delay and futility of amendment); *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993) (affirming denial of a Rule 15(a) motion based on undue delay and futility). Here, not only has NZDK unduly delayed the filing of its motion, its actions have prejudiced Defendants, and the motion is futile. Accordingly, this Court should deny NZDK’s Motion under Rule 15(a) as well.

(1) Undue Delay

“[A] movant who offers no adequate explanation for its delay will ordinarily be denied leave to amend.” *Miller Prods. Co. v. Veltek Assocs.*, 218 F.R.D. 425, 427 (D. Del. 2003) (Jordan, J.) (citing *DRR L.L.C. v. Sears, Roebuck & Co.*, 171 F.R.D. 162, 167 (D. Del. 1997)). “Thus, while bearing in mind the liberal pleading philosophy of the federal rules, the question of undue delay requires that we focus on the movant’s reasons for not amending sooner.” *Cureton v. NCAA*, 252 F.3d 267, 273 (3d Cir. 2001) (affirming a denial of a Rule 15(a) motion in part because the underlying factual information had been known long before the motion to amend was made) (citation omitted); *see also USX Corp.*, 395 F.3d at 168 (finding the fact that an individual within a corporation did not know facts available to the corporation is not a sufficient reason for delay because the court “must . . . focus on the movant’s reasons for not amending sooner in analyzing the question of undue delay”) (citation omitted).

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Focusing on NZDK's reasons for this late motion reveals the stark contours of undue delay.

NZDK does not allege that its motion is the result of information not available at the beginning of the case which later became available as a result of the discovery process.<sup>9</sup> In fact, NZDK had access to all the underlying facts *prior to filing the initial complaint*, as the information upon which it relies to add NZNA was entirely within its control. NZDK has obtained no information relevant to this motion from Defendants or third parties in the year and a half since it filed the complaint. Rather, NZDK argues it was relieved of its duty to identify all proper parties in a timely manner because NZDK did not “turn[] [its] attention to the damages phase of this bifurcated litigation” until now. *See* NZDK Brief, DI 145 at 9. However, the case was not bifurcated until seven and a half months after the complaint was filed and *two months after the deadline for all motions to join other parties* and amend or supplement the pleadings as mandated in the governing scheduling order. *See* 07/05/05 Scheduling Order, DI 32; 10/28/05 First Amended Scheduling Order, DI 70. NZDK cannot plausibly point to bifurcation as an excuse for missing a deadline that occurred before the case was bifurcated.

A motion to amend shortly before trial is also a hallmark of undue delay. *See, e.g., Averbach v. Rival Mfg. Co.*, 879 F.2d 1196, 1203 (3d Cir. 1989) (affirming denial of a motion to amend in part because motion had been filed “barely one month before the date set for trial”); *Skehan v. Board of Trustees*, 590 F.2d 470, 492 (3d Cir. 1978), *cert. denied*, 444 U.S. 832 (1979), *distinguished on other grounds*; *Smith v. City of Pittsburgh*, 764 F.2d 188 (3d Cir. 1985) (affirming denial of a motion to amend

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<sup>9</sup> NZDK cites only three cases in which courts explicitly found no undue delay under Rule 15(a). In each case, no undue delay was found because the movant had just learned information it could not have known at the beginning of the case. *See Boileau v. Bethlehem Steel Corp.*, 730 F.2d 929, 938 (3d Cir. 1984) (amendment based on *new law* that arose during a stay in the case sought by non-movant); *Callaway Golf Co. v. Dunlop Slazenger Group Ams., Inc.*, 295 F. Supp. 2d 430, 432-33 (D. Del. 2003) (Jordan, J.) (amendment based on information learned *from the other party* during discovery); *Enzo Life Scis.*, 270 F. Supp. 2d at 487-90 (amendment based on information learned *from the other party* during discovery). In the only other case NZDK cites that explicitly discussed undue delay, the court affirmed a denial of a Rule 15(a) motion for reasons that included undue delay. *See Southwestern Bell Tel. Co. v. City of El Paso*, 346 F.3d 541, 546-47 (5th Cir. 2003). While NZDK cites another case that granted a Rule 15(a) motion, this case did not explicitly examine undue delay, and did explicitly find that no prejudice or futility were present, which is different from the present instance as discussed in the next two sections. *See Kalman*, 914 F.2d at 1479-82.

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in part because movant's "motion was not filed until a short time prior to the scheduled date of trial on his remaining substantive claims"); *Lindquist*, 106 Fed. Appx. at 775-76 (affirming a Rule 15(a) denial based solely on undue delay where "the case had already been pending for two years and was ready for trial"). It is important that NZDK's fifteen month delay occurs amidst an expedited trial schedule. In fact, this motion comes only two months before trial. Because this motion has been brought at the very end of the case, and because no good reason has been stated for this delay, NZDK's motion should be denied.

(2) Prejudice to Defendants

Amending the complaint so late in this case would prejudice Defendants. Defendants have missed the chance to pursue arguments in the liability phase that might have arisen had NZNA been a plaintiff, including arguments arising from a plaintiff's decision not to market or manufacture commercial embodiments of the patent. *See Corning, Inc. v. SRU Biosystems*, No. Civ. A. 03-633 JJF, 2005 WL 2465900, at \*4 (D. Del. Oct. 5, 2005) (holding evidence of plaintiffs' commercial embodiments of the patents are "relevant to issues concerning the patent's validity, including secondary considerations regarding whether the claimed invention is obvious under 35 U.S.C. § 103"). For example, in its Post-Trial Opening Brief, NZDK argued, as support for the alleged non-obviousness of its '031 Patent, that there was an unmet need for the Spezyme® ETHYL product. *See* NZDK Post-Trial Opening Brief, DI 118 at 33; NZDK Post-Trial Reply Brief, DI 127 at 8. Had NZNA been a party to this argument, Defendants could have pointed out the hypocrisy of a manufacturer and marketer asserting unmet need in a niche it serves for a product that it believes it legally can produce, yet failed to do so. Because NZDK does not manufacture or market product in this niche, without NZNA as a party, NZDK could make this argument without contradicting its own business decisions.

Further, Defendants have also missed the opportunity to file a dispositive motion on a damages issue, the deadline for which passed on July 3, 2006. *See* 12/23/05 Stipulation, DI 78; 12/28/05 Order, DI 81. The documents so belatedly produced by NZDK offer information that NZNA is a non-exclusive licensee of the '031 Patent, and provide a basis for a summary judgment motion precluding NZDK from

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seeking the lost profits of NZNA. To withhold these documents until it was convenient for NZDK to produce, was done to the great prejudice of Defendants.<sup>10</sup>

Finally, when a party seeking to amend under Rule 15(a) has missed clear deadlines, such as those of a scheduling order, “the court finds implicit prejudice. The purpose of a scheduling order is to provide concrete deadlines on which the parties can rely in planning their respective litigation strategies.” *McLaughlin v. Diamond State Port Corp.*, No. Civ. A. 03-617 (GMS), 2004 WL 2958664, \*4 (D. Del. Dec. 21, 2004) (emphasis added). Likewise, in the current case, there was a concrete scheduling order deadline. While movant asserts the scheduling order has been modified several times, those modifications did not alter a deadline that had already passed, but rather modified future deadlines. In short, once dates on the scheduling order have passed, they have been treated as concrete. Defendants relied on this deadline in planning their litigation strategy for the entire case, including both liability and damages issues. Even after the case was bifurcated, Defendants continued to rely on the fact that this deadline had passed when making strategic decisions that affect the damages phase, including allocating depositions and interrogatories between the two phases of trial. Allowing this amendment now would prejudice Defendants, who cannot alter strategic decisions made in reliance of the scheduling order over the last year.

### (3) Futility

Where a Rule 15(a) motion for a proposed amendment seeks to add a co-plaintiff who does not have standing, “the proposed amendment would be futile and that the motion under Rule 15 must be denied.” *Site Microsurgical Sys.*, 797 F. Supp. at 333, 339. Likewise, as discussed *supra* at 8-17, NZNA does not have standing to sue in this case. As such, movant’s proposal to add this entity is futile and should not be permitted.

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<sup>10</sup> Accordingly, Defendants request permission from the Court to file a summary judgment motion on this issue at this time. Defendants respectfully submit that the trial on damages will likely need to be postponed so that the parties and the Court have time to resolve this issue prior to trial (if a trial is even necessary).

**PUBLIC VERSION – REDACTED****E. NZDK's Cursory Request Based on FRCP 15(b) Should be Denied**

Plaintiff also attempts to rely on Rule 15(b) of the Federal Rules of Civil Procedure to claim that NZNA should be added as a co-plaintiff, presenting no supporting case law and basing its argument solely on the fact that NZNA employees offered testimony at trial. However, the fact that neither party chose to assert an objection to certain evidence offered at trial does not change who owns the patent at issue in this case nor does it strip Genencor of its due process rights. NZDK's reliance on Rule 15(b) to add a new plaintiff is misplaced, as the supporting evidence offered by NZDK speaks only to its choice to contract with NZNA for its legal services in prosecuting the patent. Had NZDK contracted with an outside law firm to coordinate legal services for the patent, would the lack of objection to the trial testimony of attorneys from that firm prove the Defendant's implied consent to add the law firm as a co-plaintiff? Genencor's questioning of NZNA in-house counsel [REDACTED] at trial was indicative not of implied consent to add a new plaintiff, but of Genencor's need to solicit testimony about NZDK's patent from the attorney who prosecuted the it. Rule 15(b) simply does not provide a basis to add NZNA as a co-plaintiff.

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### CONCLUSION

For all these reasons, this Court should deny Plaintiff's Motion for Leave to Modify the Scheduling Order for the Purpose of Amending Its Complaint. Defendants also respectfully request that the Court grant them leave to file a summary judgment motion to preclude NZDK from seeking the lost profits of NZNA, and, if necessary to allow time for briefing and full consideration of the issues, delay the damages trial.

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**CERTIFICATE OF SERVICE**

I, Donald E. Reid, hereby certify that on the 25<sup>th</sup> day of August, 2006, the Public Version of Defendants' Opposition To Plaintiff's Motion For Leave To Modify The Scheduling Order For the Purpose Of Amending Its Complaint was served by e-mail upon counsel of record:

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